

REMARKS

The above-identified Application has been carefully reviewed with the Office Action of March 10, 2010, the Examiner's comments, and the art references cited therein in mind. In response thereto, Applicants submit the following arguments in support of patentability. Favorable reconsideration is hereby respectfully requested.

Claims 25-30 have been rejected under 35 U.S.C. 130(a) as being unpatentable over Gau et al (US 5,084,061) in view of Smith (US 3,238,107).

The Office Action takes the position that, Gau et al disclose an intra-gastric balloon (20) for treating obesity, for implanting in the stomach of a patient to reduce the volume of the stomach, said balloon comprising a flexible envelope (22) defining a predetermined inside volume, said flexible envelope being made of an elastomer material (col. 4, lines 6-12). While Gau et al fail to disclose a particular dimensional tolerance of the nominal thickness of the envelope of the balloon, Smith discloses a method of producing silicone elastomers which results in "extremely close dimensional tolerance" (col. 19, lines 13-50). The Office then concludes that, it would have been obvious to one of ordinary skill in the art at the time the invention was made to provide the silicone elastomer envelope of Gau et al by the method of Smith in order to provide the envelope with uniform density, excellent physical properties, and the extremely close dimensional tolerance recited by Smith. Furthermore, where Gau et al and Smith disclose the claimed invention except for the dimensional tolerance being in the range of 1-20% or 10-16%, it would have been obvious to one having ordinary skill in the art at the time the invention was made to utilize such ranges, since it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. *In re Aller*, 105 USPQ 233.

This rationale is both incomplete and improper in view of the established standards for rejections under 35 U.S.C. § 103.

In this regard, the MPEP section 2141 states:

The Supreme Court in KSR reaffirmed the familiar framework for determining obviousness as set forth in *Graham v. John Deere Co.* (383 U.S. 1, 148 USPQ 459 (1966))... As reiterated by the Supreme Court in KSR, the framework for the objective analysis for determining obviousness under 35 U.S.C. 103 is stated in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966). Obviousness is a question of law based on underlying factual inquiries. The factual inquiries enunciated by the Court are as follows:

- (A) Determining the scope and content of the prior art; and
- (B) Ascertaining the differences between the claimed invention and the prior art; and
- (C) Resolving the level of ordinary skill in the pertinent art.

In addition:

When applying 35 U.S.C. 103, the following tenets of patent law must be adhered to:

- (A) The claimed invention must be considered as a whole;
- (B) The references must be considered as a whole and must suggest the desirability and thus the obviousness of making the combination;
- (C) The references must be viewed without the benefit of impermissible hindsight vision afforded by the claimed invention and
- (D) Reasonable expectation of success is the standard with which obviousness is determined.

Hodosh v. Block Drug Co., Inc., 786 F.2d 1136, 1143 n.5, 229 USPQ 182, 187 n.5 (Fed. Cir. 1986).

As reflected above, the foregoing approach to obviousness determinations was recently confirmed by the United States Supreme Court decision in *KSR INTERNATIONAL CO. V. TELEFLEX INC. ET AL.* 550 U.S. 1, 82 USPQ2d 1385, 1395-97 (2007), where the Court stated:

In *Graham v. John Deere Co.* of Kansas City, 383 U. S. 1 (1966), the Court set out a framework for applying the statutory language of §103, language itself based on the logic of the earlier decision in *Hotchkiss v. Greenwood*, 11 How. 248 (1851), and its progeny. See 383 U. S., at 15-17. The analysis is objective:

"Under §103, the scope and content of the prior art are to be determined; differences between the prior art and the claims at issue are to be ascertained; and the level of ordinary skill in the pertinent art resolved. Against this background the obviousness or nonobviousness of the subject matter is determined. Such secondary considerations as commercial success, long felt but unsolved needs, failure of others, etc., might be utilized to give light to the

circumstances surrounding the origin of the subject matter sought to be patented." Id., at 17-18.

The Court quoting *In re Kahn*, 441 F.3d 977, 988, 78 USPQ2d 1329, 1336 (Fed. Cir. 2006), stated that "[R]ejections on obviousness cannot be sustained by mere conclusory statements; instead, there must be some articulated reasoning with some rational underpinning to support the legal conclusion of obviousness." (MPEP 2141). Simply stated, the Office Action has failed to at least (1) ascertain the differences between and prior art and the claims in issue; and (2) resolve the level of ordinary skill in the art. Furthermore, the alleged rationale for combining the references is merely an improper conclusory statement that embodies clear and improper hindsight rationale.

On pages 25 and 26 of the present application, the Applicants detail the problems inherent in forming the balloon of Gau et al. The number of steps involved requires a staff to be particularly highly qualified in the manufacture of the balloon and considerably reduces the options for associating shapes and dimensions in a single part, which amounts to limiting the functions that it can perform. Gau et al recites that his balloon will have a final thickness of approximately 0.006 to 0.025 inches. Such a variation is considerably different from the balloon produced by the Applicants where the dimensional tolerance on the nominal thickness of the envelope lies in the range of 1% to 20%. Thus, it is unquestioned that the intragastric balloon of Gau et al can result in the shell having extremely wide variations in thickness throughout the structure. This fact is admitted by the Office in the rejection and balloons produced by this method provide insufficient dimensional accuracy which can lead to certain zones of the balloon being too thick, thereby increasing the cost of producing the balloon, or to certain other zones of the balloon not being thick enough, which can lead to the balloon being fragile. This is not acceptable considering the use to which the balloon is put.

The Smith reference is offered to cure these deficiencies because Smith discloses a method of producing silicone elastomers which results in "extremely close dimensional

tolerance". A careful review of the Smith reference provides absolutely no indication what is meant by "extremely close dimensional tolerance". What that parameter meant in 1963, the filing date of the Smith reference, and what it means over 40 years later can not be determined from the reference. Thus, the Office Action has failed to determine a key factual inquiry for determining obviousness, namely, determining the scope and content of the prior art. In addition, when applying 35 U.S.C. § 103, among other considerations, the references must be considered as a whole and must suggest the desirability and thus the obviousness of making the combination. It is submitted that one of ordinary skill in the art, seeking to develop an intragastric balloon, would not undertake to search back over 40 years and select a silicone elastomer that is "useful as sealing gaskets for use in high and low temperatures and as cushioning material, particularly where both high and low temperature flexibility is desired" (col. 19, lines 47-50). The alleged rationale for combining the references is merely an improper conclusory statement that embodies clear and improper hindsight rationale, and, combines two completely non-analogous fields of endeavor. Specifically, as is well established in the law, the use of hindsight to the Appellants' own disclosure is *per se* improper. See *Crown Operations International, Ltd. v. Solutia, Inc.*, 289 F.3d 1367, 62 USPQ2d 1917 (Fed. Cir. 2002) (a determination of obviousness cannot be based on a hindsight combination of components selectively culled from the prior art to fit the parameters of the invention). Applicants respectfully submit that "it is impermissible to use the claimed invention as an instruction manual or 'template' to piece together the teaching of the prior art so that the claimed invention is rendered obvious. ... 'One cannot use hindsight reconstruction to pick and choose among isolated disclosures in the prior art to deprecate the claimed invention.'" *In re Fritch*, 972 FG.2d 1260, 1266, 23 USPQ2d 1780, 1784 (Fed. Cir. 1992). See also *In re McLaughlin*, 443 F.2d 1392, 1395 (CCPA 1971) ("[A]ny judgment on obviousness is in a sense necessarily a

reconstruction based on hindsight reasoning, but so long as it ... does not include knowledge gleaned only from applicant's disclosure, such a reconstruction is proper") (emphasis added).

Thus, it is submitted that, given the above discussion, claim 25 is in condition for allowance. Claims 26-28, depending from independent claim 25 are also believed to be in condition for allowance.

The above-recited differences indicate that the rejection of claims 29 and 30 must also fall as the product produced by the Applicants and the product produced by the proposed, and faulty, combination of Gau et al with Smith, does not produce a product that is substantially the same or similar. The remarks above point out the unobvious differences between the Applicants' intragastric balloon and any balloon that might be produced by combining Gau et al and Smith. While Smith does discuss the use of a mold and certain steps of making the silicone elastomer product, the product is useful as sealing gaskets for use at high and low temperatures and as cushioning material, particularly where both high and low temperature flexibility is desired. With regard to claim 29, the method described by the Applicants is fabricating an intragastric balloon by injecting an elastomer material into a mold in order to obtain a flexible pouch that is to form an envelope on the balloon. This is completely different from any possible combination that could be derived by one of ordinary skill in the art utilizing the Gau et al and Smith references.

Claim 30 defines further the patentable method of the Applicants and is condition for allowance based on its dependence on allowable claim 29.

CONCLUSION

With the amendments presented herein, it is believed that all the claims remaining in the Application are in condition for allowance. Early and favorable action in this regarding is hereby respectfully requested. Should there be any minor informalities remaining, the Examiner is respectfully requested to call the undersigned attorney so that this case may be passed to issue at an early date.

Respectfully submitted,



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